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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/416,735	10/13/99	ATENCIO	I CJ-08970

RICHARD B MURPHY
CANJI INC
3525 JOHN HOPKINS COURT
SAN DIEGO CA 92121

HM22/0721

EXAMINER

LEE, G

ART UNIT

PAPER NUMBER

1632

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DATE MAILED:

07/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/416,735

Applicant(s)

Atencio et al.

Examiner
Gai (Jennifer) Mi L e

Group Art Unit
1632

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-20 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-20 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2 and 16 are drawn to a method of administering p53 polypeptide to enhance apoptosis and delivered in combination with calpain inhibitor, classified in class 530, subclass 350.
 - II. Claims 1-4, 8-10, 13-16 and 18-20 are drawn to a method of administering p53 polynucleotide to enhance apoptosis and delivered in combination with calpain inhibitor, classified in class 514, subclass 44.
 - III. Claims 5-7 and 17 are drawn to a method of increasing infectivity treatment of cells with calpain inhibitor and viral vector, classified in class 424, subclass 93.6.
 - IV. Claims 11 and 12 are drawn to a method of suppressing in vivo CTL response by the administration of viral vector in combination with calpain inhibitor, classified in class 424, subclass 188.1.

Also note that claims 1-2 and 16 are generic claim to Groups I and II because the therapeutic or diagnostic compounds encompass polypeptide or polynucleotide encoding the polypeptide for use in methods of treating. The claim will be examined based on the nature of the invention elected.

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2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I and II are drawn to mutually exclusive and independent methods. Invention I is to a method of enhancing apoptosis with p53 polypeptide in combination with calpain inhibitor. Invention II is to a method of administering p53 polynucleotide encoding the polypeptide for enhancing apoptosis in combination with calpain inhibitor. The polynucleotide encoding the polypeptide and its method of administering in combination with calpain inhibitor require separate and distinct protocols from that of the polypeptide. Neither invention I or II is required for implementation of the other invention.

Inventions I and III are drawn to mutually exclusive and independent methods. Invention I is to a method of administering p53 polypeptide in combination with calpain inhibitor for enhancing apoptosis. Invention III is to a method of increasing infectivity of a cell with a viral vector (without transgene) in combination with calpain inhibitor. The two methods require separate and distinct protocols. Neither invention I or invention III is required for implementation of the other invention.

Inventions I and IV are mutually exclusive and independent methods. The method of administering p53 polypeptide in combination with calpain inhibitor of invention I is not required for the method of suppressing the in vivo CTL response to any viral vector in

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combination with calpain inhibitor of invention IV. The method of suppressing the in vivo CTL response to any viral vector in combination with calpain inhibitor of invention IV is not required for the method of administering p53 polypeptide in combination with calpain inhibitor of invention I.

Inventions II and III are drawn to mutually exclusive and independent methods. Invention I is to a method of administering a polynucleotide encoding p53 polypeptide in combination with calpain inhibitor for enhancing apoptosis. Invention III is to a method of increasing infectivity of a cell with any viral vector (without transgene) in combination with calpain inhibitor. The two methods require separate and distinct protocols. Neither invention II or invention III is required for implementation of the other invention.

Inventions II and IV are drawn to mutually exclusive and independent methods. Invention II is to a method of administering a polynucleotide encoding p53 polypeptide in combination with calpain inhibitor for enhancing apoptosis. Invention IV is to a method of suppressing the in vivo CTL response to any viral vector in combination with calpain inhibitor. The two methods require separate and distinct protocols. Neither invention II or invention IV is required for implementation of the other invention.

Inventions III and IV are drawn to mutually exclusive and independent methods. Invention III is to a method of increasing infectivity of a cell with any viral vector (without transgene) in combination with calpain inhibitor. Invention IV is to a method of suppressing the in vivo CTL response to any viral vector in combination with calpain inhibitor. The two

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methods require separate and distinct protocols. Neither invention III or invention IV is required for implementation of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Mr. Murphy on 07/06/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gai (Jennifer) Mi Lee whose telephone is (703) 306-5881. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Gai (Jennifer) Mi Lee
Patent Examiner
Group 1600

Gai Mi Lee
Patent Examiner
1632